Docket No. 22956-71
(PATENT)

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Ian D. McRury et al.

Application No. 10/024,625

Filed: December 18, 2001

For: SUTURE WELDING SYSTEM AND METHOD

Confirmation No. 3998

Art Unit: 3731

Examiner: Darwin P. Erezo

Boston, Massachusetts
February 6, 2009

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDED APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is Ethicon, Inc. located in Somerville, New Jersey. Ethicon, Inc. derives its rights in this application by virtue of an assignment of the application by the inventors to Ethicon, Inc.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1, 3-8, 20-21, and 23-34 are currently pending in the present application. Claims 2, 9-19, and 22 have been canceled. Accordingly, claims 1, 3-8, 20-21, and 23-34 are subject to this appeal.

IV. STATUS OF AMENDMENTS

Applicant has submitted an Amendment under 37 CFR 41.33 to correct the dependency of claim 23 as suggested by the Examiner, address the indefiniteness rejections of claims 3, 20 and 31 as suggested by the Examiner, and to submit formal drawings.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to systems, devices and methods for welding lengths of suture to create a fixed attachment between lengths of suture without tying knots. In particular, the invention provides systems, devices and methods for welding a first length of suture to a second length of suture to create a fixed attachment between the two lengths of suture.

A. Independent Claim 1 Provides a Welding System Using RF Energy for Fixedly Attaching a First Length of Suture to a Second Length of Suture at a Suture Welding Site

Applicant's claim 1 recites a suture welding system 10 for fixedly attaching a first length of suture 176 to a second length of suture 178 at a suture welding site. The system includes an electrosurgical energy source 32 configured to generate radio waves; first and second lengths of suture 176, 178; and a suture welding device 12. The suture welding device 12 has a working end 20; a suture contacting element 18 located on the working end 20 and having the first and second lengths of suture 176, 178 disposed thereon; a first electrode 26 electrically coupled to

the electrosurgical energy source 32 and disposed on the suture contacting element 18 for providing radio frequency energy to the first and second lengths of suture 176, 178; and a second electrode 28 electrically coupled to the electrosurgical energy source 32 and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source. Provision of radio frequency energy by the first electrode 26 to the first and second lengths of suture 176, 178 welds the first and second lengths of suture 176, 178 into a fixed attachment. [Page 5, line 13 to page 6, line 12; page 10, lines 28 to 33.]

B. Independent Claim 20 Provides a Method Using Electrosurgical Energy for Welding a First Length of Suture to a Second Length of Suture to Create a Fixed Attachment Therebetween

Applicant's claim 20 recites a method for welding a first length of suture 176 to a second length of suture 178 to create a fixed attachment therebetween. The method includes providing an electrosurgical energy source 32 and a suture welding device 12. The suture welding device 12 has a working end 20; a suture contacting element 18 disposed on the working end 20, the suture contacting element 18 having two opposing faces having a variable gap therebetween, each face having an electrode 26, 28 disposed thereon. The first electrode 26 is electrically coupled to the electrosurgical energy source 32 and disposed on the suture contacting element 18 for providing electrical energy to the first and second lengths of suture 176, 178. The second electrode 28 is electrically coupled to the electrosurgical energy source 32 and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source 32. The method also includes placing a first length of suture 176 and a second length of suture 178 into contact with the suture contacting element 18; and providing energy from the electrosurgical energy source 32 through the first electrode 26 to the first and second lengths of suture 176, 178 to weld the first length of suture 176 to the second length of suture 178 to create a fixed attachment therebetween. [Page 5, line 13 to page 6, line 12; page 12, lines 17 to 29; page 14, lines 20 to 27.]

C. Independent Claim 29 Provides a Welding System Using Electrosurgical Energy for Fixedly Attaching a First Length of Suture to a Second Length of Suture at a Suture Welding Site

Applicant's claim 29 recites a suture welding system 10 for fixedly attaching a first length of suture 176 to a second length of suture 178 at a suture welding site. The system

includes an electrosurgical energy source 32 and a suture welding device 12. The suture welding device 12 has a working end 20; a suture contacting element 18 disposed on the working end; a first electrode 26 electrically coupled to the electrosurgical energy source 32 and disposed on the suture contacting element 18 for providing electrical energy to the first and second lengths of suture 176, 178; and a second electrode 28 electrically coupled to the electrosurgical energy source 32 and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source 32. The suture contacting element 18 also has at least one pod 172 configured to prevent the first and second sutures 176, 178 from sliding off of the suture contacting element 18. Provision of electrical energy by the first electrode 26 to the first and second lengths of suture 176, 178 welds the first and second lengths of suture 176, 178 into a fixed attachment. [Page 5, line 13 to page 6, line 12; page 8, lines 4 to 28; page 11, line 29 to page 12, line 4.]

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Rejections Under 35 USC §102 of Claims 1, 3-6, 20-21 and 23-34

The Examiner has rejected claims 1, 3-6, 20-21 and 23-34 under 35 USC 102(b) as being anticipated by Egan '880 (US 5,893,880).

B. Rejections Under 35 USC §103 of Claims 7 and 8

The Examiner has rejected claim 7 under 35 USC 103(a) as being unpatenable over Egan '880 (US 5,893,880) in view of Fenton (US 6,403,743 to Fenton Jr.); and claim 8 under 35 USC 103(a) as being unpatenable over Egan '880 (US 5,893,880) in view of Rydell (US 5,342,359).

C. Rejections Under 35 USC §112 of Claims 3, 20, 21, 23-26, and 31-33

The Examiner has rejected claims 3, 20, 21, 23-26, and 31-33 under 35 USC §112, second paragraph, as being indefinite.

VII. ARGUMENT

Applicant traverses each of the bases for rejecting the claims.

A. To Rebut the Rejections, It is Important to Understand the Context in Which the Invention was Made, As Well as the Long Procedural History of This Case

To fully understand the claimed invention and its relationship to the ultrasonic welding references cited by the Examiner, it is first necessary to appreciate the state-of-the-art at the time of Appellant's invention (including those same references), which represents the background against which the claimed invention was developed.

1. The Problem Addressed by the Invention is the Difficulty in Forming Knots in Sutures

Many surgical procedures include the use of sutures, particularly for tissue fixation and repair, and often in endoscopic, arthroscopic or other minimally invasive procedures for effecting surgical procedures within a patient's body. Traditionally, once a suture is appropriately positioned with respect to the relevant tissue, the suture ends are knotted together to fix or otherwise repair the tissue. However, knots may be difficult to make, difficult to properly tension and difficult to properly place, particularly in tight spaces. (Page 1, lines 8-17.)

Suture fixation techniques other than knotting, such as frictional welding, have been tried. Frictional welding is generally accomplished by exposing the suture material to ultrasonic energy. Recent examples of this approach are disclosed in patents to Axya Medical, Inc. of Beverly, Massachusetts, including U.S. Patent Nos. 5,417,700; 5,893,880; and 6,174,324; which relate to methods and systems using the application of ultrasonic energy to weld sutures. (Page 1, lines 18-25.) In fact, various Examiners have cited the ultrasonic welding patents of Axya Medical in Office actions during the prosecution of this application (including the citation of US 6,358,271 to Egan et al. in previous Office actions, and the citation of US 6,409,743 to Fenton, Jr. in the outstanding rejection addressed here on appeal). The present inventors have discovered, however, that ultrasonic welding does not work well with all popular suture materials, and proper welding can be sensitive to suture placement and configuration within the welding device. (Page 1, lines 18-27.)

Accordingly, there remains a need to fix sutures without the need to tie knots. In particular, it would be desirable to develop a system to weld lengths of popular suture materials,

especially polydioxanone (PDS), a popular suture material for which existing welding methods are insufficient.

2. The Invention Solves the Problem by Providing a Suture Welding System for Fixedly Attaching a First Length of Suture to a Second Length of Suture

The claimed invention allows sutures to be attached without knots by providing systems and methods useful for welding a first length of suture to a second length of suture to create a fixed attachment between the two lengths of suture. In general, the first and second lengths of suture are welded into a fixed attachment by providing electrosurgical energy (in particular, radio frequency, or RF, electrosurgical energy) to the two lengths of suture. (Page 2, lines 4-15.) FIG. 1 of the application, reproduced below, shows a schematic representation of the suture welding system 10, including an energy source 32 and a suture welding device 12. The suture welding device 12 also includes a suture grasper or suture contacting element 18 on its distal working end. (Page 5, lines 20-26.)

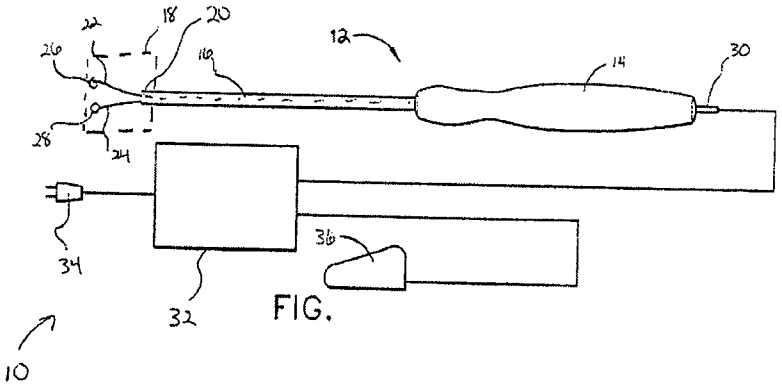


FIG.

FIG. 1

FIGS. 2A and 2B of the application, reproduced below, show a side view of a suture grasper in open and closed configurations. As illustrated in the Figures, the suture grasper includes a first suture grasping member 150 and second grasping member 152, each of which includes an electrode; 170 and 180 respectively. (Page 8, lines 4-28).

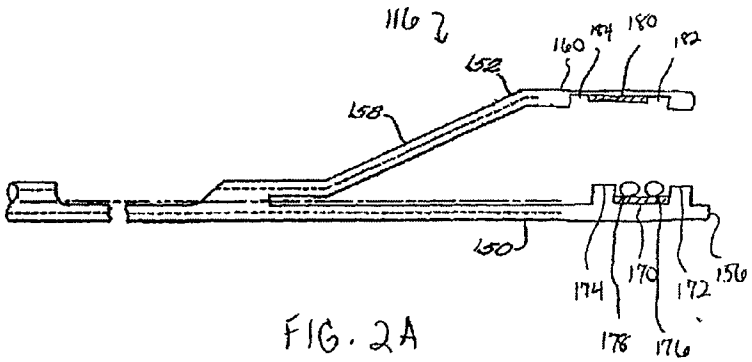


FIG. 2A

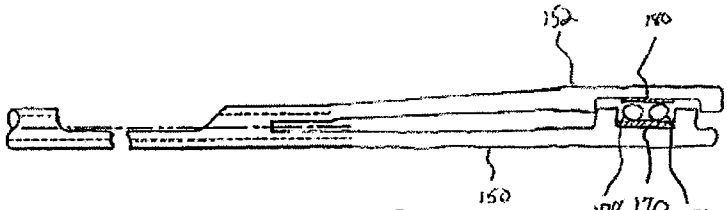


FIG. 2B

Also shown in the Figures are two lengths of suture 176, 178 which are held in contact with the electrodes 178, 180 when the suture grasper 116 is placed in a closed position for welding. (Page 8, line 30 – page 9, line 14.)

FIG. 2C, reproduced below, shows a side view of the suture grasper 116 in a fully closed position with two lengths of suture 176, 178 tightly held within the grasper in close contact with electrodes 170, 180. (Page 9, lines 16-18.)

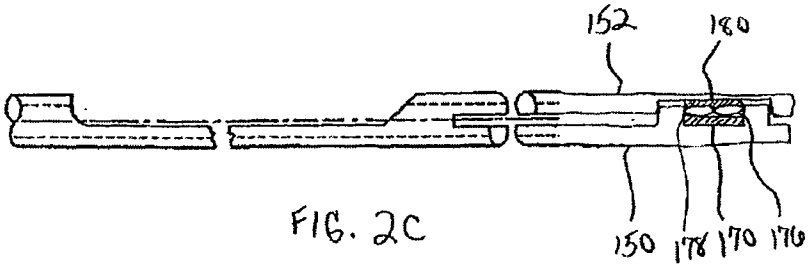


FIG. 2C

Although the lengths of suture 176, 178 are illustrated in FIG. 2C as being deformed due to pressure applied to them by opposed electrodes 170, 180, such deformation may or may not occur depending on the properties of the suture material and the amount of pressure applied. However, it is desirable that there be close physical contact between the electrodes 170, 180 and the lengths of suture 176, 178. (Page 9, lines 18-23.) Electrical energy, preferably in the form of radio frequency or RF energy, can thus be provided to the lengths of suture 176, 178 by the

electrodes 170, 180 so as to weld the lengths of suture into a fixed attachment. (Page 2, lines 10-15, and page 6, lines 5-12.)

3. Prosecution in this Case has been Improperly Re-Opened After Applicant's Prior Appeal Brief

By Applicant's count, this application has been subject to 11 office actions – 10 on the merits – and including at least 7 where ultrasonic welding references related to the Egan reference now relied upon by the Examiner were applied. The following is a summary of these actions:

Date	Event	Significance
12/18/01	Filing	Application filing date; Axya Medical patents re ultrasonic welding described in the Background of the application, including Egan '700; ***Egan '880***; and Egan '324 patents.
12/18/01	IDS	Citing 11 references including Egan '700; ***Egan '880***; Egan 545; and Egan '324 patents.
03/05/04	Non-Final Office Action	Claims rejected over Morris, Tetzlaff, Rydell, and Doddi references. ***The Egan '271 (the disclosure of which is a CIP of Egan '880)*** and Fenton '088 references were ***considered pertinent but not relied upon***.
06/18/04	Amendment	Applicants mail amendment with claim amendments and argument
11/02/04	Final Office Action	Claims finally rejected over Morris, Tetzlaff, Rydell, and Doddi references and adds ***rejections over*** Egan '324 and ***Egan '271 (the disclosure of which is a CIP of Egan '880) – Examiner states that "Egan does not disclose radio frequency waves as an energy source . . ." Examiner combines Egan with RF cautery tools.***
12/31/04	Amendment	Applicants mail amendment in response to final, minor amendments made (1st and 2nd lengths of suture are amended to be "separate") and ***Egan ultrasonic energy is distinguished from Applicants' RF electrosurgical energy.***
01/26/05	Advisory Action	Amendment not entered.
03/01/05	RCE Filed	RCE filed to have previous Amendment entered.
04/12/05	Non-Final Office Action	Examiner maintains rejections.
09/07/05	Interview	Focus on ***obviousness combination of RF electrosurgical energy with Egan.***
09/12/05	Amendment	***All claims amended to include RF electrosurgical energy and arguments re combination with Egan made.***
11/28/05	Restriction Requirement	
12/23/05	Amendment	Applicants mail response to restriction requirement.

03/16/06	Final Office Action	Claims finally rejected over Polonsky and Doddi references (no ultrasonic references cited).
05/16/06	Amendment	Applicants mail response – the only amendment is to change the dependency of claim 34; references distinguished through argument.
06/09/06	Non-Final Office Action	New non-final office action over Fenton '743 and Hulka. ***Fenton '743 (Axya ultrasonic) is said to disclose the substitution of electrical, RF energy for ultrasonic***, while Hulka provides the details of an electrical RF device.
10/06/06	Amendment	Applicants mail amendment, no claim amendments are made, Applicants only argue with respect to obviousness rejections.
01/04/07	Final Office Action	The Examiner stands on the obviousness rejections, but notes: ***"The rejection under this section has been rewritten to more clearly elaborate on how the Fenton [Axya ultrasonic] reference is being interpreted."***
03/05/07	Amendment	Applicants mail Amendment in which no claim amendments are made, ***only argument is presented over the obviousness rejection based on the new interpretation of Fenton '743 (Axya ultrasonic).***
03/26/07	Advisory Action	***Applicants arguments are said to be unpersuasive.***
06/04/07	Pre-Appeal Conference	***Applicants file pre-appeal brief conference request summarizing arguments from previous Amendment.***
09/13/07	Panel Decision	***The panel found "at least one actual issue for appeal" and directed that the matter should go to the Board.***
12/13/07	Appeal Brief	***Applicants file appeal brief with arguments made in Pre-Appeal Conference Request and Amendment in response to the Final Office Action.***
06/11/08	Non-Final Office Action	All but one claim now rejected as ***anticipated by Egan '880***, the same Axya ultrasonic technology that has been cited throughout the previous 10 office actions on the merits and in contrast to the Examiner's express admission and the SPE's implicit admission in recommending Applicant's arguments for appeal.

To be clear – the Egan '880 reference that is the current source of an anticipation rejection, is described in the Background section of the application and has been of record since it was cited by Applicant in 2001. Claim rejections over the Axya Medical ultrasonic welding technology (of which the Egan '880 reference is a part) have been made or maintained 7 times, with the rejections 4 of those times being over the child of the Egan '880 reference. Applicant has held an interview, filed 6 amendments, filed a pre-appeal brief conference request, and filed an appeal brief to address the obviousness arguments over these references. The result of this effort has been to have prosecution re-opened as Applicant's arguments have finally been

deemed persuasive – but now the claims are rejected as anticipated by technology that the claims are not obvious over.

The original rejections applied the child of the Egan '880 reference, with the Examiner stating "Egan does not disclose radio frequency waves as an energy source . . ." [November 2, 2004 Final Office Action at p. 7.] Accordingly, the Egan reference was combined with an RF cautery tool to make out an obviousness rejection. Applicant overcame this obviousness rejection, and the Examiner moved on to a different ultrasonic welding reference that, itself, mentioned RF energy as an alternative – again making only obviousness rejections. Applicant fully rebutted this rejection. Now the claims are said to be anticipated by the very same technology that the claims are not obvious over.

B. All Rejections Should be Withdrawn as Estopped

The making of the outstanding rejections in light of the history of this application violates clear PTO policy and practice.

1. The Examiner Should Be Estopped From Taking an Entirely New (and Contradictory) Approach After 10 Office Actions and an Appeal

Throughout the first 10 office actions in this case, the facts could not have been more clear. The ultrasonic welding references of record did not anticipate the claims that applied RF electrosurgical energy through electrodes. These references are described in the Background of the application and have been of record since the filing of this application in 2001. They have been applied only as obviousness references throughout. The Examiner, the same Examiner who issued the most recent office action, has expressly stated on the record that "Egan does not disclose radio frequency waves as an energy source . . ." Now, the Examiner has taken the completely opposite view that the parent of that Egan reference that did not disclose radio frequency waves as an energy source, anticipates the claims reciting radio frequency waves.

The MPEP and case law are silent on this topic, probably because this situation cannot occur if the Patent Office is functioning properly. However, the MPEP does note that when more than one examiner is involved in a case, full faith and credit should be given to the search and actions of the previous examiner. [MPEP 706.04.] Subsequent examiners should not take

an entirely new approach or attempt to reorient the point of view of the previous examiner, and may only do so in the case of clear error on the part of the previous examiner. [*Id.*]

Here, the Examiner does not give full faith and credit to the seven years of prosecution history in which he, himself, is the major participant. If those seven years of prosecution were a clear error on the part of the Examiner, Applicant would like to be refunded its fees. In any event, the outstanding rejection is improper and should be withdrawn.

2. The SPE Should Be Estopped From Re-Opening Prosecution Over Old References that have Already Been Distinguished in Prosecution

a. It is Improper to Re-Open Prosecution After Denying the Pre-Appeal Brief Conference Request Based on the Same Arguments

Applicant's previous appeal brief in this case was the fifth time that Applicant made the same arguments against the combination of the Fenton and Hulka references. Applicant argued only in response to the June 9, 2006 rejection applying these references. Applicant provided the same arguments in response to the Examiner's making final of those rejections. Applicant provided the same arguments in a Pre-Appeal Brief Conference Request following the Examiner's Advisory Action. When the Examiner informed Applicant that there was at least one appealable issue for presentation to the Board, Applicant filed the same arguments again for the fifth time in an Appeal Brief. If the SPE was going to re-open prosecution because the arguments were persuasive, she never should have allowed the case to go to appeal in the first place.

The *Official Gazette* notice establishing the pre-appeal brief conference request process [United States Patent and Trademark Office, *Official Gazette*, July 12 2005, http://www.uspto.gov/go/og/2005/week28/patbref.htm] outlines the four possible outcomes of the pre-appeal brief conference: (1) the application remains under appeal because there is at least one actual issue for appeal, (2) prosecution on the merits is re-opened, (3) the application is allowed and prosecution is closed, or (4) the request fails to comply with the submission requirements and is dismissed. *Id.*

While the second finding above gives the examiner the option to re-open prosecution immediately after the pre-appeal brief conference, the *Official Gazette* notice indicates that the

examiner retains the option to re-open prosecution after the filing of an appeal brief. *Id.* The publication explains that this is an "unlikely situation" that might arise in cases where new arguments are presented in the appeal brief. *Id.*

Applicant's prior brief did not raise new arguments and the re-opening of prosecution mentions none – it simply says that the arguments presented (for the fifth time) are persuasive. Accordingly, there is no basis for re-opening prosecution after the appeal brief and the SPE should be estopped from doing so.

b. It is Improper to Re-Open Prosecution After the Appeal Brief to Reject over a Reference that has been of Record for Seven Years and that is Insubstantially Different from the References Cited Repeatedly Leading Up to Appeal

The requirements from the MPEP for re-opening prosecution after an appeal brief has been filed are (1) that there be a new ground of rejection and (2) that the supervisory patent examiner approve of the action. *See MPEP § 1207.* Here, the first prong is not met.

The MPEP defines a new ground of rejection in the negative by stating that there is no new ground when the basic thrust of the rejection remains the same. *MPEP 1207.03(III).* The key concern is whether the applicant has been given a chance to respond to the rejection. *See In re Kronig*, 539 F.2d 1300, 1302-03 (C.C.P.A. 1976). The MPEP further notes that where the statutory basis and evidence relied upon remains the same a simple change in the discussion of the rejection does not constitute a new ground of rejection. *MPEP 1207.03(III).*

Here, there has been no new evidence, and the change in statutory basis from section 103 to section 102 is a false one as the Examiner has already admitted that anticipation is not made out on these facts. As there is no new ground for the rejection, prosecution has been improperly re-opened and the previous Appeal, which the SPE has found to be persuasive, should be ruled on. If the Examiner wants to re-characterize references that have been of record for 7 years, he can do so in his Examiner's Answer and the Board can rule.

Nor does the newly made "indefiniteness" rejection qualify as new grounds – the claims have been unamended through several years and several rejections without any mention of indefiniteness. No facts have changed in this regard, only the Examiner's mind.

C. Egan '880 Renders No Claim From the Claim 1 Group of Claims Unpatentable

The Egan '880 patent is mere background to the present invention and lacks several elements of the independent claim such that anticipation is impossible.

1. Egan '880 Discloses an Ultrasonic Vibrating Device; There is no RF Electrosugical Energy and No Electrodes

Egan sets as its background, the art of ultrasonic welding of sutures:

> Polymer sutures are particularly amenable to various fusing or joining processes, such as, for example, welding, whereby sections of the sutures can be fused together upon application of sufficient heat to the sections to cause partial melting and fusion of the sections. Because the direct application of heat to sutures in situ may produce undesirable heating of the surrounding tissue, it is preferred to apply non-thermal energy to the suture material in situ to induce localized heating of the suture material in the areas or sections to be fused. In particular, ultrasonic energy may be effectively applied to sections of suture materials to induce frictional heating of the sections in order to fuse or weld them together.
>
> * * *
>
> Although ultrasonic welding of sutures is known, it has heretofore been difficult or impossible to control the suture welding process in order to produce suture welds of sufficient strength and reliability to replace, or enhance the strength of, suture knots or other loop closure devices.
>
> It is therefore an object of the present invention to overcome the disadvantages inherent in prior art suture loop joints and joining processes. [Col. 1, line 33 to col. 2, line 6.]

Egan's brief description of its device for fusing is based on the following:

> FIGS. 10A-14B illustrate various geometries for ultrasonic welding apparatus, and more particularly for the vibratory and stationary members of an ultrasonic welding tip, which includes a first member 30 and a second member 32. The ***first member 30 is capable of vibrating and delivering mechanical energy at ultrasonic frequencies, as is known in the art***. The first member 30 is movable relative to the second member 32, so that a gap or space can be defined between the first and second members. The

gap is sufficiently large to accommodate two or more segments 16, 18 of material to be joined together. The ultrasonic welding apparatus further includes fixture means for aligning and maintaining the segments 16, 18 in a predetermined alignment and orientation during the welding process. [Col. 8, lines 8 to 20; emphasis added.]

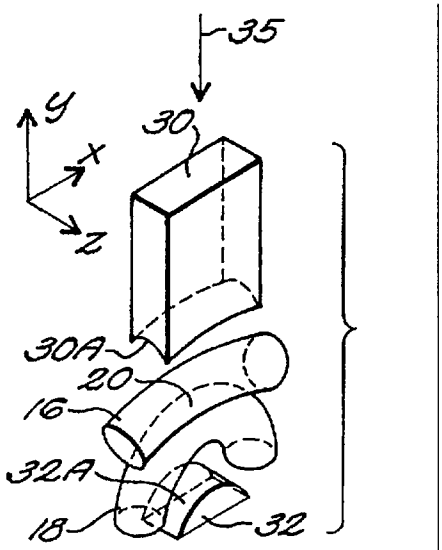


FIG. 10A

Egan is crystal clear – its apparatus uses a vibrating part 30 and an anvil 32 to impart mechanical energy to induce localized heating. There is no electrical energy, there are no radio frequencies, and there are no electrodes.

2. Egan '880 Cannot Anticipate Claim 1 under 35 USC 102 as it Discloses None of the Key Features of the Claim

Claim 1 recites, *inter alia*,

- an ***electrosurgical energy source*** configured to generate ***radio frequency waves***;
- a ***first electrode electrically coupled*** to the ***electrosurgical energy source*** and disposed on the suture contacting element for ***providing radio frequency energy*** to the first and second lengths of suture; and
- a ***second electrode electrically coupled*** to the ***electrosurgical energy source*** and disposable proximate to the suture welding site for ***providing a return electrical energy path*** to the electrosurgical energy source.

Egan '880 discloses none of these features.

a. Egan Fails to Disclose an Electrosurgical Energy Source

According to the Examiner, Egan discloses "an electrosurgical energy source (col. 5, ll. 30-33)." That portion of Egan does not disclose an electrosurgical energy source[1] – instead, it discloses:

> The fused loop of the present invention is preferably formed through a welding process, in which segments of the material to be joined are locally heated through the application of energy thereto until the segments fuse together.

b. Egan Fails to Radio Frequency Electrosurgical Energy

According to the Examiner, Egan discloses an electrosurgical energy source "configured to generate radio frequency waves (col. 8, ll. 13; ultrasonic sound is sound pressure waves whose frequency is above the audible range, which has an upper limit of 20 KHz)." Column 8, line 13 of Egan states that "[t]he first member 30 is capable of vibrating and delivering mechanical energy at ultrasonic frequencies, as is known in the art." There is ***no*** "***electrosurgical energy source*** configured to generate ***radio frequency waves***," there is ***instead*** a vibrating member that delivers ***mechanical energy*** at ***ultrasonic frequencies***.

The Examiner's assertion that mechanical energy delivered at ultrasonic frequencies and electrosurgical energy delivered at RF frequencies are equivalent is wrong. The application notes that standard electrosurgical energy sources used for electrocautery cutting and coagulation tools can be used, and states, at page 6, lines 10-12, that,

> As used herein, the term radio frequency refers to frequencies that are higher than those used in cutting/coagulating applications, and are preferably

[1] Egan notes that a variety of welding techniques exist in general, and that among these are "electric arc discharge." Even if it were relied upon by the Examiner, this would not be a disclosure of an electrosurgical energy source generating radio frequency waves – for example, an electric arc discharge could be created by discharging a capacitor. In addition, the disclosure of an electric arc discharge cannot be used as part of an anticipation rejection as a matter of law since there is no such system disclosed, and a reference must not only disclose all of the elements of a claim, but must also disclose those elements 'arranged as in the claim.'" Net Moneyin, Inc. v. Verisign, Inc., 2008 U.S. App. LEXIS 21827, p. 22 (Fed. Cir. October 20, 2008) (quoting Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983)).

> between about 100KHz and 1MHz, and more preferably between about 300KHz and 500KHz.

A vibrating member is not a source of electrosurgical energy and is not configured to deliver energy at these frequencies. While Egan is entirely silent as to frequency (other than using the word ultrasonic – and thus may have its own issues with enablement), the person of ordinary skill in the art would not expect it to operate at these frequencies as a mechanical vibrating member operating at these frequencies would generate significant heat – a problem that Egan (quoted above from Egan's background) has expressly set out to avoid.

The Egan patentees agree that ultrasonic energy and radio frequency electrical energy are alternatives – not the same thing. Indeed, the Fenton patent cited by the Examiner (Fenton is a co-inventor on the Egan '880 patent) expressly recognizes this difference. Fenton (US 6,409,743) provides:

> In one embodiment of the fusing tool, ***the energy source is ultrasonic energy***.
>
> * * *
>
> In ***alternate embodiments, energy for bonding is supplied by*** thermal energy (e.g., heat), optical energy (e.g., laser generated), ***electrical energy (e.g., radio frequency, RF)***, or current sources (e.g., resistive heating). [Col. 2, line 64 to col. 3, line 9.]

RF electrical energy is not the same thing as ultrasonic energy – it is an "alternate embodiment."

Further, as has been repeated extensively above, the Examiner himself has stated in this application that "Egan does not disclose radio frequency waves as an energy source . . ." This was precisely why the Examiner used Fenton as the primary reference in previous rejections (that the Applicant has overcome), because it does suggest the use of RF electrical energy.

It seems that we all agree – Egan does not disclose an electrosurgical energy source configured to generate radio frequency waves.

*c. Egan Fails to Disclose "a First **Electrode Electrically** Coupled to the **Electrosurgical Energy Source**," "for Providing Radio Frequency Energy" to the Sutures*

Claim 1 recites "an electrosurgical energy source configured to generate radio frequency waves" and "a first electrode electrically coupled to the electrosurgical energy source . . . for providing radiofrequency energy to the first and second lengths of suture." The structure recited is clear – the electrosurgical energy source generates radio frequency waves that are coupled through an electrical connection to an electrode for delivery to the sutures. Egan does not disclose, teach, or suggest this.

According to the Examiner, Egan discloses a suture welding system having:

> a first 30 and second electrode 32, wherein the first electrode 30 receives energy and vibrates and deliver ultrasonic frequency to the suture and back to the second electrode (col. 8, II. 12-14);

The Examiner's explanation ignores the clear language of the claim. There must be an electrosurgical energy source configured to generate radio frequency waves (Egan has none) to which an electrode (Egan has a vibrating member) is electrically coupled (Egan has a mechanical coupling) to provide the radio frequency energy generated by the electrosurgical energy source to the sutures (Egan delivers mechanical energy, not RF energy generated by an electrosurgical energy source). The electrode so recited in claim 1 is missing entirely from Egan.

*d. Egan Fails to Disclose "a Second **Electrode Electrically** Coupled to the **Electrosurgical Energy Source**," "for Providing a **Return Electrical Energy Path** to the Electrosurgical Energy Source"*

Claim 1 recites "an electrosurgical energy source configured to generate radio frequency waves" and "a first electrode electrically coupled to the electrosurgical energy source . . . for providing radiofrequency energy to the first and second lengths of suture." After the RF electrosurgical energy is applied to the sutures by the first electrode, a "second electrode electrically coupled to the electrosurgical energy source" provides "a return electrical energy path to the electrosurgical energy source." The structure recited is clear – the electrosurgical energy source generates radio frequency waves that are coupled through an electrical connection to an electrode for delivery to the sutures, and a second, return electrode that completes a return

electrical energy path to the electrosurgical energy source (to which the second electrode is coupled). Egan does not disclose, teach, or suggest this.

According to the Examiner, Egan discloses a suture welding system having:

> a first 30 and second electrode 32, wherein the first electrode 30 receives energy and vibrates and ***deliver ultrasonic frequency to the suture and back to the second electrode*** (col. 8, II. 12-14);

The Examiner's explanation ignores the clear language of the claim that ***the second electrode is electrically coupled to the electrosurgical energy source to provide a return electrical path***. Egan does no such thing.

As noted above, there must be an electrosurgical energy source configured to generate radio frequency waves (Egan has none) to which an electrode (Egan has a vibrating member) is electrically coupled (Egan has a mechanical coupling) to provide the radio frequency energy generated by the electrosurgical energy source to the sutures (Egan delivers mechanical energy, not RF energy generated by an electrosurgical energy source). In addition, there must be a second electrode (Egan has an anvil) that is electrically coupled (Egan's anvil is not so coupled) to the electrosurgical energy source generating radio frequency waves (Egan has none) to provide a return electrical energy path (Egan does not deliver electrical energy and provides no such path – just a vibrating member and an anvil for delivering mechanical energy. The second electrode and return electrical energy path recited in claim 1 is missing entirely from Egan.

e. Conclusion: Egan Cannot Anticipate Claim 1

Most of the recitations of claim 1 are missing from Egan because Egan supplies mechanical energy to the sutures by ultrasonic vibration as opposed to the claim which applies electrical energy through electrical couplings through electrodes in a bi-polar fashion with a second electrode providing a return electrical path to the source. This electrical energy is supplied in the form of RF waves. Applicant, Egan's co-inventor, and the Examiner himself have all agreed on this point. Egan cannot anticipate claim 1.

3. Claim 6, Reciting Polydioxanone Sutures, is Not Anticipated by Egan under 35 USC 102

Applicants' claim 6 recites that the first and second lengths of suture that are made of polydioxanone. Egan mentions polydioxanone sutures at column 2, lines 25 to 29. The present inventors have found that existing suture welding methods, including the ultrasonic welding disclosed by Egan, do not work with polydioxanone sutures. For example, the background of the present invention discloses that:

> Suture fixation techniques other than knotting have also been tried. For example, techniques and apparatus for performing frictional suture welding have been disclosed. Such frictional welding is generally accomplished by exposing the suture fixturing and/or **directly exposing the suture material to ultrasonic energy**. U.S. Pat. No. 3,515,848 to Winston et al. discloses devices and methods for ultrasonic suture welding. More recently, patents assigned to Axya Medical, Inc. of Beverly, Mass. (see, e.g., U.S. Pat. Nos. 5,417,700; 5,893,880; 6,174,324) have disclosed devices and methods involving the application of ultrasonic energy to weld sutures. This method, however, **does not work with all popular suture materials, and proper welding can be sensitive to suture placement and configuration within the welding device**.

An express goal of the claimed invention, the first suture welding device of its type, is to employ radio frequency waves in order to facilitate the welding of polydioxanone sutures. Egan's approach does not address the problems with welding of polydioxanone sutures because Egan never recognizes the problem (and as a result is not enabling for welding this suture material).

By virtue of its dependence from the independent claim, claim 6 recites that polydioxanone sutures that are welded to each other by the delivery of RF energy through the recited suture welding devices. Egan does not disclose, teach or suggest such welding. Rather, Egan teaches that any elongate thing that can be joined together by the application of heat can be welded ultrasonically.

There is no teaching or suggest anywhere in any cited reference to the successful welding of polydioxanone sutures, and so no disclosure, teaching or suggestion of claim and 6 which

supply RF energy to lengths of polydioxanone sutures to weld them to each other. Accordingly, claim 6 is further patentable over Egan.

4. Claim 8, Reciting a Movable Piston, is Not Obvious over Egan in view Rydell of under 35 USC 103

Claim 8 recites that the suture welding device includes a piston slidingly disposed on the suture welding device so as to be translatable in a longitudinal direction to move the first and second lengths of suture into contact with at least one electrode. Egan teaches a vibrating member for vibrating the two lengths of suture to create frictional heating therebetween. If a sliding piston were to push the sutures up against the anvil (which the Examiner analogize with an electrode) – the vibrating member could not now cause that frictional heating as the sutures would be pushed by the piston into contact with the anvil. Such a modification to Egan would plainly render it unsuitable for its intended purpose.

According to MPEP § 2143.01(V), "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the propose modification" (citation omitted). Further, in accordance with MPEP § 2143.01(VI), "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious" (citation omitted). Here, the purpose of Egan is to use vibrating member 30 to deliver mechanical energy to the sutures to weld them together by frictional heating – using a piston to hold the sutures would frustrate that purpose and render Egan useless. Accordingly, the modification cannot be made and claim 8 is further patentable for this reason.

5. Claim 28, Depending from Claim 1 and Reciting a Pod for Holding the Sutures, is Not Anticipated by Egan under 35 USC 102

Claim 28 recites that the suture contacting element has at least one pod configured to prevent the first and second sutures from sliding off the suture contacting element. As shown in FIG. 2A of the present application, reproduced below, the pods 172, 174 are specific structures that prevent the sutures from sliding off the suture contacting element.

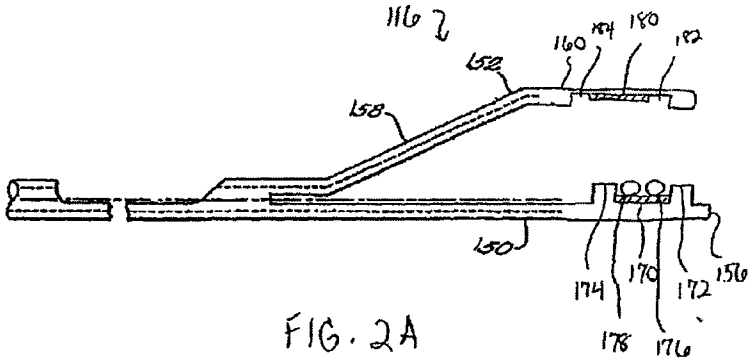


FIG. 2A

The Examiner argues that "[t]he suture contacting element comprises element 32, as shown in Fig. 19B, which is viewed as a pod for preventing the first and second sutures from sliding off of the suture contacting element." However, the Examiner also asserts that element 32 is the second electrode, and presumably also the suture contacting element (because it is the only structure that contacts the suture), and it is said to perform triple duty as a pod also. This interpretation of Egan makes no sense. The claim requires a working end having a suture contacting element and electrodes, and further having one or more pods configured to prevent the sutures from sliding off of the suture contacting element. Figure 19B of Egan shows a two piece anvil that is closed around the sutures so that vibrating member 30 can impart mechanical energy to them. The Examiner never says what the suture contacting element is, identifies the anvil as an electrode, and says the electrode is also the pod. The claim elements are simply not there.

D. Egan '880 Renders No Claim From the Claim 20 Group of Method Claims Unpatentable

Applicant's claim 20 recites, *inter alia*, a ***method*** for welding a first length of suture to a second length of suture to create a fixed attachment therebetween. Because this independent claim recites a method, the interrelationship between the elements are recited as actions, making the arguments for method claim 20 even stronger than those made above for claim 1. Claim 20 recites:

- providing a suture welding device having:
  - a suture contacting element
  - a first electrode . . . disposed on the suture contacting element for providing electrical energy to the first and second lengths of suture

- a second electrode . . . . for providing a return electrical energy path

- placing a first length of suture and a second length of suture into contact with the suture contacting element

- providing energy from the electrosurgical energy source through the first electrode to the first and second lengths of suture to weld the first length of suture to the second length of suture

Each and every argument provided with respect to claim 1 above applies with equal or greater force to claim 20 which recites action where the system claim of claim 1 recites structure and function.

1. Egan '880 Discloses an Ultrasonic Vibrating Device; There is no RF Electrosugical Energy and No Electrodes; and Thus No Anticipation of Claim 20 Under 35 USC 102

The rejection of claim 20 is essentially the same as it is for claim 1, and it fails for many of the same reasons. The Examiner points to no disclosure of an electrosurgical energy source, no first electrode, no second electrode, and no step of applying energy from the electrosurgical energy source through the first electrode to the first and second lengths of suture to weld them together. There can thus be no anticipation of claim 20 by Egan.

2. Egan '880 Does not Disclose an Electrosurgical Energy Source Generating Radio Frequency Waves; and Thus There is No Anticipation of Claim 21 Under 35 USC 102

Egan, as described extensively above, does not provide any disclosure, teaching, or suggestion of an electrosurgical energy source generating radio frequency waves. Accordingly, claim 21 is further patentable for this reason.

3. Egan '880 Does not Disclose a Pod for Preventing the Sutures from Sliding Off of the Suture Contacting Element; and Thus There is No Anticipation of Claim 25 Under 35 USC 102

Egan, as described above with respect to claim 28, does not provide any disclosure, teaching, or suggestion of the recited pod. Accordingly, claim 25 is further patentable for this reason.

4. Egan '880 Does not Disclose the Welding of Polydioxanone Sutures; and Thus There is No Anticipation of Claim 26 Under 35 USC 102

Egan, as described above with respect to claim 6, does not provide any disclosure, teaching, or suggestion of the welding of polydioxanone suture. Accordingly, claim 26 is further patentable for this reason.

E. Egan '880 Renders No Claim From the Claim 29 Group of System Claims Unpatentable

Applicant's claim 29 recites, *inter alia*, a system for welding a first length of suture to a second length of suture to create a fixed attachment therebetween. Claim 29 includes many of the elements of claim 1 (though the electrosurgical energy source is not configured to generate radio frequency waves in claim 29 – it is in dependent claim 30 – instead, claim 29 recites the ***provision of electrical energy to the sutures***), and further includes pods as recited in claim 28 discussed above. Claim 29 recites, *inter alia*:

- an ***electrosurgical energy source***;
- a ***first electrode electrically coupled*** to the ***electrosurgical energy source*** and disposed on the suture contacting element for ***providing electrical energy*** to the first and second lengths of suture;
- a ***second electrode electrically coupled*** to the ***electrosurgical energy source*** and disposable proximate to the suture welding site for ***providing a return electrical energy path*** to the electrosurgical energy source;
- the suture contacting element having ***at least one pod configured to prevent the first and second sutures from sliding off*** of the suture contacting element.

Egan '880 discloses none of these features.

1. Egan '880 Discloses No Electrodes Delivering *Electrical Energy* to the Sutures; and Thus No Anticipation of Claim 29 Under 35 USC 102

In addition to all of the reasons recited for claim 1 above, and also claim 28 reciting at least one pod, claim 29 has a further recitation that is ignored by the Examiner. The Examiner merely states that Egan applies as it does to claims 1 and 28. The Examiner does not address the limitation that the first electrode provides ***electrical energy*** to the first and second lengths of

suture. Egan plainly has no electrode and provides only mechanical energy to the sutures. Claim 29 is further patentable over Egan for this reason.

2. Egan '880 Does not Disclose an Electrosurgical Energy Source Generating Radio Frequency Waves; and Thus There is No Anticipation of Claim 30 Under 35 USC 102

Egan, as described extensively above, does not provide any disclosure, teaching, or suggestion of an electrosurgical energy source generating radio frequency waves. Accordingly, claim 30 is further patentable for this reason.

3. Egan '880 Does not Disclose the Welding of Polydioxanone Sutures; and Thus There is No Anticipation of Claim 34 Under 35 USC 102

Egan, as described above with respect to claim 6, does not provide any disclosure, teaching, or suggestion of the welding of polydioxanone suture. Accordingly, claim 34 is further patentable for this reason.

F. Claims 3, 20 and 31 Are Not Indefinite

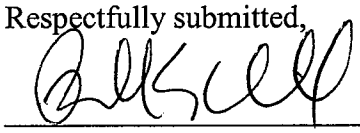
The Examiner asserts that claims 3, 20, and 31 are indefinite. Applicant asserts that these claims are definite, as the Examiner himself has had no problem understanding their meaning – both in this office action and in the several office actions over the past several years that have included the identical claims. This rejection has never been made until now. In any event, Applicant has submitted an Amendment to address this issue as the Examiner suggests in the office action.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Dated: February 6, 2009

Respectfully submitted,



Ronald E. Cahill
Reg. No. 38,403
Attorney for Appellant
NUTTER McCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2699
Telephone: (617) 439-2550
Facsimile : (617) 310-9550

CLAIMS APPENDIX

1. (Previously Presented) A suture welding system for fixedly attaching a first length of suture to a second length of suture at a suture welding site, comprising:

an electrosurgical energy source configured to generate radio frequency waves;

first and second lengths of suture; and

a suture welding device, having:

a working end;

a suture contacting element located on the working end and having the first and second lengths of suture disposed thereon;

a first electrode electrically coupled to the electrosurgical energy source and disposed on the suture contacting element for providing radio frequency energy to the first and second lengths of suture; and

a second electrode electrically coupled to the electrosurgical energy source and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source;

wherein provision of radio frequency energy by the first electrode to the first and second lengths of suture welds the first and second lengths of suture into a fixed attachment.

2. (Canceled)

3. (Previously Presented) The system according to claim 1 wherein the suture contacting element comprises two opposing faces having a variable gap therebetween, each face having one of the first electrode or second electrode disposed thereon.

4. (Original) The system according to claim 3 wherein the suture welding device is configured to be selectively adjustable between an open position and a closed position, wherein the first and second lengths of suture may be placed within the variable gap in the open position and wherein the lengths of suture are constrained within the variable gap in the closed position.

5. (Original) The system according to claim 1 wherein the first and second lengths of suture are made of material selected from the group consisting of polydioxanone, prolene, and polymer plastics.

6. (Original) The system according to claim 1 wherein the first and second lengths of suture are made of polydioxanone.

7. (Previously Presented) The system according to claim 1 wherein a weldable material is provided between at least one electrode and at least one length of suture, the weldable material adapted to weld the first length of suture thread to the second length of suture thread upon application of radio frequency energy through the at least one electrode.

8. (Previously Presented) The suture welding device of claim 1,

wherein the suture welding device includes a piston slidingly disposed on the suture welding device so as to be translatable in a longitudinal direction to move the first and second lengths of suture into contact with at least one electrode.

9-19. (Canceled)

20. (Previously Presented) A method for welding a first length of suture to a second length of suture to create a fixed attachment therebetween, comprising:

(a) providing an electrosurgical energy source;

(b) providing a suture welding device, having:

a working end;

a suture contacting element disposed on the working end, the suture contacting element having two opposing faces having a variable gap therebetween, each face having one of a first electrode or a second electrode disposed thereon;

the first electrode electrically coupled to the electrosurgical energy source and disposed on the suture contacting element for providing electrical energy to the first and second lengths of suture; and

a second electrode electrically coupled to the electrosurgical energy source and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source;

(c) placing a first length of suture and a second length of suture into contact with the suture contacting element; and

(d) providing energy from the electrosurgical energy source through the first electrode to the first and second lengths of suture to weld the first length of suture to the second length of suture to create a fixed attachment therebetween.

21. (Previously Presented) The method of claim 20 wherein the electrosurgical energy source generates radio frequency waves.

22. (Canceled)

23. (Previously Presented) The method of claim 21 wherein the suture welding device is configured to be selectively adjustable between an open position and a closed position, wherein the first and second lengths of suture may be placed within the variable gap in the open position and wherein the lengths of suture are constrained within the variable gap in the closed position.

24. (Previously Presented) The method of claim 23 wherein the suture contacting element forces the first and second lengths of suture into close physical contact with each other when the suture welding device is placed in the closed position.

25. (Previously Presented) The method of claim 20 wherein the suture contacting element has at least one pod configured to prevent the first and second sutures from sliding off of the suture contacting element.

26. (Previously Presented) The method of claim 20 wherein the first and second lengths of suture are made from polydioxanone.

27. (Previously Presented) The system of claim 4 wherein the suture contacting element is configured to force the first and second length of suture into close physical contact when the suture welding device is placed in the closed position.

28. (Previously Presented) The system of claim 1 wherein the suture contacting element has at least one pod configured to prevent the first and second sutures from sliding off of the suture contacting element.

29. (Previously Presented) A suture welding system for fixedly attaching a first length of suture to a second length of suture at a suture welding site, comprising:

an electrosurgical energy source; and

a suture welding device, having:

a working end;

a suture contacting element disposed on the working end, the suture contacting element having at least one pod configured to prevent the first and second sutures from sliding off of the suture contacting element;

a first electrode electrically coupled to the electrosurgical energy source and disposed on the suture contacting element for providing electrical energy to the first and second lengths of suture; and

a second electrode electrically coupled to the electrosurgical energy source and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source;

wherein provision of electrical energy by the first electrode to the first and second lengths of suture welds the first and second lengths of suture into a fixed attachment.

30. (Previously Presented) The system of claim 29 wherein the electrosurgical energy source generates radio frequency waves.

31. (Previously Presented) The system of claim 29 wherein the suture contacting element comprises two opposing faces having a variable gap therebetween, each face having one of the first electrode or the second electrode disposed thereon.

32. (Previously Presented) The system of claim 31 wherein the suture welding device is configured to be selectively adjustable between an open position and a closed position, wherein the first and second lengths of suture may be placed within the variable gap in the open position and wherein the lengths of suture are constrained within the variable gap in the closed position.

33. (Previously Presented) The system of claim 32 wherein the suture contacting element is configured to force the first and second length of suture into close physical contact when the suture welding device is placed in the closed position.

34. (Previously Presented) The system of claim 29, wherein the first and second lengths of suture are made of polydioxanone.

EVIDENCE APPENDIX

No evidence has been submitted.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

1798966.1